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Congress of the United States

House of Representatives
Washington, DC 20515-2107

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Tom Scully
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Scully:

This letter is in reference to the Outcome and Assessment Information Set (OASIS) a program designed to create a standardized assessment for Home Health Agencies (HHAs) for the purposes of quality control and financial oversight that was implemented July 19, 1999.

As you know, the OASIS assessment is a seventeen-page assessment tool of highly specific questions regarding very sensitive topics including detailed health, mental health and financial information. The OASIS assessment information is collected from every home health patient who is a Medicare or Medicaid beneficiary and transmitted to the Centers for Medicare and Medicaid Services (CMS) formerly known as the Health Care Finance Administration (HCFA). The program also requires the collection and transmission of OASIS information -- in a de-identified form -- of non-Medicare and non-Medicaid patients served by a certified home health agency. However, the transmission of this information is currently not required as the final rule has yet to be published.

Originally, OASIS information on non-Medicare and non-Medicaid patients was to be collected and transmitted to CMS in an identifiable form. In the spring of 1999, I had several meetings with Health Care Finance Administrator Nancy-Ann Min Di Parle to discuss my privacy concerns with respect to the OASIS survey tool. We also discussed my opposition to the collection and transmission of this highly sensitive personally identifiable health information from non-Medicare and non-Medicaid patients who personally stood to gain nothing from having this information collected. Ultimately, HCFA took steps to improve the survey and reversed its plans to collect non-Medicare or non-Medicaid information in identifiable form. This was a step in the right direction with respect to privacy.

Today, however, I continue to have privacy concerns with the collection of OASIS data and am particularly concerned that this information is collected without the consent, as patient consent is not a requirement. And while it is required that patients be informed of their privacy rights I have learned that this is often not the case. Recently, I have heard

from home health nurses who are uncomfortable and often unable to collect accurate OASIS information. The information they have provided me – which I will summarize more fully below – raises issues regarding the accuracy and ultimately the worth of this information, as well as new privacy concerns that were not evident prior to implementation of the program. In addition, two GAO reports raise issues with respect to privacy protection of information collected through Medicare. These reports are entitled Medicare: Improvements Needed to Enhance Protection of Confidential Information, (GAO/HEHS-99-140), and Medicare Home Health Care: OASIS Data Use, Cost, and Privacy Implications, GAO-01-205).

It is my understanding that CMS is authorized to implement the OASIS program for the purpose of evaluating outcomes of treatment through section 1891(d) of the Social Security Act which requires the Secretary of the Department of Health and Human Services to “designate an assessment instrument (or instruments) for use by an agency in complying with subsection (c)(2)(C)(I).” In addition, Section (c)(2)(C)(iii) requires that the survey be carried out by someone who is not serving on the staff of the home health agency and who has no personal or familial interest in the home health agency surveyed.

Currently, home health agencies (HHAs) are required by CMS to use the OASIS tool for reimbursement through the prospective payment system. Given that the OASIS data set was originally designed as an outcomes assessment tool would you please provide answers to the following:

- 1) How did the OASIS data set evolve from an outcomes assessment tool to a reimbursement tool?
- 2) Would you please cite the statute that gives CMS the authority to require HHAs to collect this sensitive information for reimbursement purposes?
- 3) Would you please cite the statute that gives CMS the authority to collect OASIS information from non-Medicare and non-Medicaid patients?

Regarding section 1891(d) of the Social Security Act that states, “Not later than January 1, 1992, the Secretary shall – evaluate the assessment process, (ii) report to Congress on the results of such evaluation, and (iii) based on such evaluation, make such modifications in the assessment process as the Secretary determines are appropriate,” would you please provide questions to the following:

- 1) Have any evaluations of the OASIS program occurred since its initiation?
- 2) If so, has the Secretary taken appropriate steps to modify the assessment process?

With respect to the GAO reports cited above, the first report (GAO/HEHS-99-140) points out that CMS “cannot readily provide beneficiaries with an accounting of the disclosures it makes, a capability called for by the Privacy Act,” and “does not routinely monitor

contractors and others, such as researchers, who use personally identifiable Medicare information.” would you please explain the following:

- 1) What steps has CMS taken to address its lack of compliance with the Privacy Act?
- 2) What steps has CMS taken to establish policies and procedures that would provide for effective routine monitoring of contractors and others, such as researchers, who use personally identifiable Medicare information?

The second GAO report cited in this letter (GAO-01-205) notes that a nurse’s start-of-care visit will “include explanations of privacy rights as well as patient care.” This would include an explanation of the right that non-Medicare and non-Medicaid patients have to opt-out of answering the OASIS questions. In informal discussions with several home health nurses, it has been brought to the attention of my staff that nurses often don’t have time to inform home health patients of their privacy rights or the circumstances surrounding the treatment of the individual may make a discussion of privacy difficult or even inappropriate. For example, informing the patient of her privacy rights at the “start-of-care” is not a priority in the case where a patient comes home from the hospital, in terrible pain with the diagnosis of a terminal illness. In such a situation, the home health nurse’s primary concern is to care for the patient’s immediate physical needs. Given the scope of the information collected under OASIS and the likelihood that a patient may not have an opportunity to learn of her privacy rights let alone give consent for the collection of this sensitive data, would you please provide responses to the following questions:

- 1) How does CMS enforce compliance with the OASIS privacy requirements?
- 2) Why are Medicare and Medicaid patients not required to sign a form granting consent for the collection of their sensitive medical information?
- 3) Why are non-Medicare and non-Medicaid patients not required to sign a form granting consent for the collection of their sensitive medical information?
- 4) If a Medicare or Medicaid patient refuses to comply with the requirement that the OASIS information be collected and specifically requests that the questionnaire be left blank, will the patient then be refused care?
- 5) If a non-Medicare or non-Medicaid patient refuses to comply with the requirement that OASIS information be collected and specifically requests that the questionnaire be left blank, will the patient then be refused care?
- 6) Is there any evidence that home health nurses conducting these surveys simply fill in the OASIS survey without the knowledge of the patient in order to assure a patient’s treatment and ultimately payment for the service? If so, how often does this happen and to what degree does this influence the overall accuracy of the data?

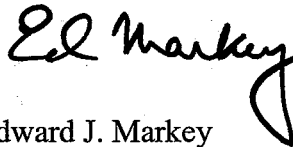
Nurses have also expressed that many of the questions are irrelevant with respect to the specific care being provided to many of the patients. For example if a patient is being treated post-operatively for a foot ulcer – the questions related to lifespan, the patient's ability to do his or her own laundry and who pays the patient's bills would appear to be irrelevant. Given that many of these questions also may often be unnecessarily intrusive with respect to the privacy rights of these patients, would you please respond to the following questions:

- 1) Has CMS considered modifying the survey in order to make it less intrusive?
- 2) Has CMS considered allowing home health agencies more flexibility with respect to which questions they choose to ask, given that some situations may not merit detailed questions regarding lifespan, mental health, or living conditions?

Finally, with respect to the security of the information collected, the GAO report notes HCFA's claim that it "has... implemented data transmission and storage policies to protect the information while it is in transit to, and being stored at, state agencies and HCFA." In a footnote, the GAO comments: "We have not reviewed the implementation of the system, and without testing the security mechanisms in place at HCFA, state agencies, and HHAs, we cannot be assured the steps taken will adequately protect the privacy of non-Medicare/Medicaid patients." (GAO-01-205 p.16) Given this information would you please explain what steps have been taken by CMS to assure that the security of this information is protected, so that the privacy of these patients is not compromised?

I thank you for your prompt attention to this letter and ask for a response no later than June 25, 2002.

Sincerely,

A handwritten signature in dark ink, appearing to read "Ed Markey", with a stylized flourish at the end.

Edward J. Markey